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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,752	03/09/2001	Gerhard Schmidmaier	8932-148	8071

20582 7590 06/30/2003

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/30/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,752

Applicant(s)

SCHMIDMAIER ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 5. 6) ☐ Other:

DETAILED ACTION

Status of the Application

Receipt of the Declaration and Fee and the Information Disclosure Statement (IDS), both filed 06/04/01 and the IDS filed 03/09/01 is acknowledged.

Claims 1-31 are pending. Claims 1-31 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 4, 5, 10 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "varnish-like" in claims 1, 4, 5, 10 and 31 is indefinite because it is unclear as to how the term "varnish" would be distinguished or distinct from the term "varnish-like". The terms appear to be equivalent. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1615

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-12, 16, 17, 21-23 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Arm *et al.* (WO 93/20859).

Arm *et al.* disclose implants and prosthetic devices having an outer surface coated with biodegradable polymeric films, which comprise polylactic acid/polyglycolic acid copolymers, therapeutically effective amounts of growth factors, active agents and carriers, wherein the polymeric films have a preferred thicknesses of less than about 50 microns. The films may be affixed to the outer surface of the implant or prosthetic device, which include a screw, pin, plate, rod or artificial joint component. The films and rods are therapeutically useful for promoting tissue growth and repair, particularly for enhancing repair of bone fractures (see page 3 line 32 through page 7, line 10) and abstract and claims.

Claims 1, 2, 4, 5, 8-10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Eitenmuller *et al.* (US Pat. No. 4,610,692).

Eitenmuller disclose an implant for filling bone cavities and fixing bone fragments in a living body comprising at least one coating of predetermined thickness, about 4 microns to about 30 microns, of a biodegradable substance selected from at least one of polymethacrylate, polylactide, polydextran and cellulose-based substances, wherein the implant also comprises at least one therapeutically active ingredient (see reference

Art Unit: 1615

column 3, line 10 through col. 4, line 36); (col. 6, lines 14-25); (col. 7, lines 23-44); and claims.

Claims 1-6, 8-12 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Healy *et al.* (US Pat. No. 5,670,161).

Healy disclose an expandable, biodegradable stent for use within a body lumen comprising a hollow tube made from a copolymer of L-lactide and caprolactone, wherein the stent incorporates surface coatings or thin films having a thickness of about 25 microns and whereby suitable polymers include polyethylene glycol, polyvinyl alcohol, polyvinyl pyrrolidone, polymethacrylic acid and polyacrylamide that are blended and copolymerized with biodegradable materials. The film may coat only surfaces of the stent or may extend over the micro-machined perforations in the stent. The stent may also desirably incorporate one or more drugs, growth factors and inhibitors (see reference column 5, lines 27-60); (col. 10, lines 10-48); and claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-15, 18, 19 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arm et al. (WO 93/20859).

Arm et al., as discussed above, teaches implants and prosthetic devices having an outer surface coated with biodegradable polymeric films, which comprise polylactic acid/polyglycolic acid copolymers, therapeutically effective amounts of growth factors, active agents and carriers, wherein the polymeric films have a preferred thicknesses of less than about 50 microns. The films may be affixed to the outer surface of the implant or prosthetic device, which include a screw, pin, plate, rod or artificial joint component. The films and rods are therapeutically useful for promoting tissue growth and repair, particularly for enhancing repair of bone fractures (see page 3 line 32 through page 7, line 10) and abstract and claims.

According to Arm, degradation of the film and consequent release of growth factors there from can be modulated by adjusting such film parameters as molecular weight, copolymer structure, copolymer ratio and thickness. In general, the film will be formulated using a copolymer having a molecular weight between 10,000 and 200,000 Daltons. Film thicknesses of less than about 50 microns are preferred. Figure 1

Art Unit: 1615

illustrates a 40-50 micron film of PLA/PGA random copolymer of approximately 100,000 molecular weight (page 6, line 28 through page 7, line 5).

Suitable polypeptide growth factors include PDGF, TGF-alpha, TGF-beta, IGF-I, bFGF, aFGF, EGF and the like. Growth factors may be used singly or in combination with one another (page 7, line 6-17). Suitable biodegradable polyester films include polylactic acid, polyglycolic acid, polydioxanone or polylactic acid/polyglycolic acid copolymer films (page 5, lines 10-19).

In addition to the copolymers, growth factors and carriers, the biodegradable films may include other active or inert components. Of particular interest are those agents that promote tissue growth or infiltration. Agents that promote bone growth, such as morphogenic proteins, osteogenin and NaF, for example can be included (page 11, line 32 through page 12, line 4).

Regarding the amount of polymer employed per ml of solvent, Arm in Example 1, page 15, demonstrates the teaching of polylactic acid and polylactic acid-polyglycolic acid films that were solvent cast by dissolving approximately 340 mg of polymer granules in 10 ml of chloroform at room temperature and allowing the solvent to evaporate completely in an air hood.

With respect to the instant percentages (0.1-10%) and instant combinations of growth factor, it appears that the amounts taught by Arm (0.0375 and 1.5 micrograms per mg of copolymer – pg 12, lines 13-24) fall within the applicant's claimed ranges. Furthermore, one of ordinary skill in the art could determine suitable ranges through routine or manipulative experimentation to obtain the best possible results. There is no

Art Unit: 1615

criticality seen in the amounts of growth factor employed since Arm explicitly teaches similar amounts for a similarly intended purpose. Furthermore, there is no criticality seen in the particular combination of growth factors, since Arm clearly suggests at page 7, lines 8-10, that the growth factors may be used singly or in combination. One of ordinary skill would select a suitable growth factor or a combination of growth factors, based on the intended purpose at hand.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

June 27, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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